UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In re: Nexium (Esomeprazole Magnesium) Antitrust Litigation This Document Relates to: ALL ACTIONS	MDL No. 2409 Civil Action No. 1:12-md-02409-WGY

PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION *IN LIMINE* TO EXCLUDE EVIDENCE OF FOREIGN SALES OF GENERIC NEXIUM (ECF NO. 1133)

Defendants' motion *in limine* to exclude evidence of widespread foreign sales of generic Nexium (*see* attached Exhibits 1, 2, showing where generic Nexium is sold and by whom) is an improper attempt to prevent the jury from hearing relevant evidence regarding the capabilities of Teva to come to the market but for its agreement with AstraZeneca and should be denied. The motion is also premature. Plaintiffs believe the better course is for the Court to address this issue in a concrete context when it arises.

Evidence of Foreign Sales of Generic Nexium is Relevant

As this Court acknowledged in its Memorandum and Order setting forth its reasoning regarding its summary judgment orders, ECF No. 977 ("Summary Judgment Memorandum"), "[w]hether Teva actually was close to obtaining approval is hotly disputed by the parties." Summary Judgment Memorandum at 124. Evidence that Teva and other companies have been able to successfully formulate, manufacture, and launch generic Nexium in numerous other countries, and evidence that those companies have been able to continue selling generic Nexium in those markets over several years, is relevant evidence of Teva's capabilities *as a company* to manufacture and sell generic Nexium when it wishes to do so. This is the very definition of relevance under Fed. R. Evid. 401.

Defendants claim that this evidence "is not probative of when or whether *the FDA* would approve Teva's ANDA product…." ECF No. 1134, Defs. Mem. at 1 (emphasis added). But Plaintiffs are not attempting to use the evidence to prove what *the FDA* would have done, but rather what *Teva* is capable of doing. This Court has recognized that "the timing and content of the change in tone of Teva's internal communications and documents, as well as Teva's agreement to set May 27, 2014 as a new proposed launch date, provide ample grounds for a reasonable juror to conclude that Teva was well on its way to obtaining tentative approval as of early 2008, and that it has since slowed its progress in response to the terms of its settlement with AstraZeneca." Summary Judgment Memorandum at 124-25. The success of Teva and other companies launching generic Nexium in numerous other countries certainly can inform the jury about what *Teva* was capable of doing when it wished to.[1]

Evidence of Foreign Sales of Generic Nexium Will Not Confuse the Jury or Require Additional Chemical Evidence

Defendants want to prevent the jury from hearing relevant evidence regarding foreign sales of Nexium under Fed. R. Evid. 403 because they believe that it will be too confusing. "Because Rule 403 requires the exclusion of relevant evidence, it is an extraordinary measure that should be used sparingly,"[2] and the Court should decline to do so here. Defendants themselves are trying to create confusion by suggesting that evidence of foreign sales of generic Nexium by Teva and others will somehow imply that the FDA would have given Teva approval because other countries have done so. That is not the purpose of this evidence. Rather, as stated

[1] Defendants suggest that Nexium sold abroad is actually a different drug than what is sold in the United States. Defs. Mem. at 2. This is purely attorney argument – Defendants have provided no declaration or other means of testing the veracity of their assertion. Certainly the Court here is not required to take defense counsels' word that the drug sold under the same name and with the same active ingredient in other countries is so different than what is sold in the United States that a generic company's development, manufacture, and launch of such a drug in another country is completely irrelevant to its ability to do so in the United States.

[2] *Campbell v. Keystone Aerial Surveys*, 138 F.3d 996, 1004 (5th Cir. 1998).

above, the evidence is probative of what *Teva* is capable of, and what *Teva* can do when not delaying pursuant to an agreement with AstraZeneca, not what the FDA would have done.

Defendants cite to product liability cases wherein courts have excluded evidence of decisions and determinations of foreign regulatory bodies regarding the safety of certain products *that differ from the decisions and determinations of the FDA*. In those cases, although a company may have comported with FDA regulations, foreign regulations may have been more strict than those of the FDA. In those cases, the courts have excluded the evidence to prevent confusion about the *defendants' duties*. Again, here, evidence of Teva's selling generic Nexium in other countries goes to Teva's abilities as a company – Plaintiffs are not arguing that this evidence shows what the FDA would or would not do.

Defendants also suggest that the introduction of the evidence of foreign sales will require them to rely on additional chemical evidence regarding the formulation of Nexium in foreign countries. Not so. This would only be arguably necessary if Plaintiffs tried to use the evidence of foreign sales to show that the generic Nexium sold in other countries is approvable by the FDA in the United States. But again, Defendants' protestations are unwarranted and an attempt to exclude relevant evidence by creating confusion about the nature and purpose of that evidence.

There Is Primary Evidence and Appropriate Expert Disclosure Regarding the Foreign Sales

Finally, Defendants argue that there is no primary evidence of or appropriate expert disclosure of foreign sales. That is wrong. Plaintiffs submitted a declaration on March 27, 2014 containing extensive primary evidence of foreign sales of generic Nexium, including the summary chart that also appears in Mr. Morrison's expert report, as support for Plaintiffs' Reply Memorandum in Support of Their Motion for Reconsideration as to AstraZeneca's and

Ranbaxy's Motions for Summary Judgment Due to Lack of Causation Based on New Evidence (ECF No. 891). Moreover, Teva's own publicly-filed Form 20-F filings with the United States Securities and Exchange Commission refer to Teva's foreign launches of generic Nexium.

Regarding expert testimony, Mr. Morrison's supplemental report was already challenged by Defendants with a Motion to Exclude (ECF No. 1011), and this Court denied that motion.[3] Mr. Morrison observes that generic Nexium has been marketed in foreign countries.

Moreover, the fact that the Generic Defendants in this case have launched and continue to sell generic Nexium in foreign countries is not subject to reasonable dispute because the underlying facts are contained in sources whose accuracy cannot reasonably be questioned.

Specifically, at the appropriate time, Plaintiffs may seek to introduce the following facts into evidence:

1. Teva launched a generic Nexium product in Germany in 2010. This fact is stated in Teva Pharmaceutical Industries Limited's Form 20-F for year ending December 31, 2010 that was filed with the United States Securities and Exchange Commission at pages 23-24. In that filing, Teva states with respect to Germany that "[In 2010, we launched 24 generic versions of the following branded products in Europe…Nexium® (esomeprazole magnesium dehydrate)…" The pertinent portions of Teva's Form 20-F are attached as Exhibit 3.

2. Teva launched a generic Nexium product in United Kingdom and Italy in 2011. These facts are stated in Teva Pharmaceutical Industries Limited's Form 20-F for the year ending December 31, 2011 that was filed with the United States Securities and Exchange Commission at page 30. In that filing, with respect to Italy, Teva states "In 2011 we launched 29 new molecules. Among others, we launched the generic versions of … Nexium®

[3] Transcript of Final Pretrial Hearing, September 30, 2014, at p. 36.

(esomeprazole)… With respect to the United Kingdom, Teva states "[i]n 2011, we launched 30 new products or new dosage forms, including the generic versions of Nexium® (esomeprazole)…" The pertinent portions of the Form 20-F are attached as Exhibit 4.

3. Teva launched a generic Nexium product in France in 2012. This fact is stated in Teva Pharmaceutical Industries Limited's Form 20-F for the year ending December 31, 2012 that was filed with the United States Securities and Exchange Commission at page 32. In that filing, with respect to France, Teva states "[i]n 2012, we launched 52 new products or dosage forms, including the generic versions of …Nexium® (esomeprazole)…" The pertinent portions of the Form 20-F are attached as Exhibit 5.

4. Teva sells a generic Nexium product in Ireland. This fact is reflected in the database of Reimbursable Items that is maintained by the Primary Care Reimbursement Services of the Health Services Executive,[4] *available at* http://www.sspcrs.ie/druglist/search.jsp/pub. The search results obtained in this database by searching for "esomeprazole" are attached as Exhibit 6.

5. Teva sells a generic Nexium product in Denmark. This fact is reflected in the database of medicinal product prices (medicinpriser.dk) maintained by the Danish Medicines Agency (Lægemiddelstyrelsen), *available at* http://www.medicinpriser.dk/?lng=2. The search results obtained by searching by active substance for "esomprazol" are attached as Exhibit 7.

6. Teva sells a generic Nexium product in Belgium. This fact is reflected in the "Répertoire Commenté des Medicaments" for 2013 published by the Belgian Centre for Pharmacotherapeutic Information (Centre Belge d'Information Pharmacothérapeutique),

[4] The Health Services Executive is an organization responsible for running all the public health services in Ireland. *See* http://www.practicemanager.ie/page.php?id=10&title=Structure.

available at http://www.bcfi.be/pdf/ggr/GGR_FR_2013.pdf. The page from this publication reflecting that Teva sells a generic Nexium is attached as Exhibit 8.

7. Teva, through Ratiopharm,[5] sells a generic Nexium product in Luxembourg. This fact is reflected in the list of medications marketed in Luxembourg as of March 1, 2014 provided by the National Health Fund (CNS),[6] *available at* http://cns.lu/files/listepos/14.03_Liste_comm.pdf. The page from this publication reflecting that Ratiopharm sells a generic Nexium is attached as Exhibit 9.

8. Teva, through Mepha Pharma AG,[7] sells a generic Nexium product in Switzerland. This fact is reflected in a search by active agent (Wirkstoff) for "esomeprazolum" in the Specialty List database maintained by the Federal Office for Public Health (BAG), *available at* http://bag.e-mediat.net/SL2007.Web.External/. The search results are attached as Exhibit 10.

9. Teva, through Ratiopharm,[8] and Ranbaxy, sell a generic Nexium product in Finland. These facts are reflected in the database of (FimeaWeb) maintained by the Finnish Medicines Agency (Fimea),[9] *available at* http://www.fimea.fi/medicines/fimeaweb. The search results obtained by searching by active substance for "esomeprazol" in the database are attached as Exhibit 11.

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[5] Ratiopharm was acquired by Teva in 2010 and is now a subsidiary of Teva. *See* Ex. 3 at 8, 17 and 48.

[6] The National Health Fund is the central contact point for all insured persons in the private sector as well as public sector workers, for health insurance and long-term care insurance. *See* http://www.guichet.public.lu/entreprises/en/organismes/cns/index.html.

[7] Teva acquired Cephalon and its Swiss-based Mepha generic business. *See* Ex. 4 at 29.

[8] *See* note 2, *supra*.

[9] The Finnish Medicines Agency Fimea is the national competent authority for regulating pharmaceuticals. *See* http://www.fimea.fi/about_us.

10. Ranbaxy sells a generic Nexium in Italy. This fact is reflected in the transparency list for the reimbursement of equivalent drugs (Liste di Trasparenza) as updated April 15, 2014 maintained by the Italian Pharmaceutical Agency (AIFA),[10] *available at* http://www.agenziafarmaco.gov.it/sites/default/files/Lista_equivalenti_per_Principio_Attivo_15.04.2014_aggiornamento.pdf. The relevant pages are attached as Exhibit 12

11. Teva, through Ratiopharm,[11] and Ranbaxy sell a generic Nexium product in Portugal. These facts are reflected in http://www.infarmed.pt/infomed/pesquisa.php by searching by active substance for "esomeprazol" in the Informed database maintained by the National Authority of Medicines and Health Products (INFARMED, I.P.).[12] The search results are attached as Exhibit 13.

13. Teva and Ranbaxy sell a generic Nexium in Spain. These facts are reflected in a search by active ingredient for "esomeprazole" in the AEMPS Medicines Online Information Center - CIMA database maintained by the Spanish Agency for Medicines and Health Products (AEMPS), *available at* http://www.aemps.gob.es/cima/pestanias.do?metodo=accesoAplicacion. The search results are attached as Exhibit 14.

14. Teva and Ranbaxy sell a generic Nexium in Sweden. These facts are reflected in a search for "esomeprazole" in the database maintained by the Dental and

[10] The AIFA is the national authority responsible for the regulation of drugs in Italy. *See* http://www.agenziafarmaco.com/en/node/4111.

[11] Ratiopharm was acquired by Teva in 2010 and is now a subsidiary of Teva. *See* Ex. 3 at 8, 17 and 48.

[12] The National Authority of Medicines and Health Products is a government agency. Its "objective is to monitor, assess and regulate all activities relating to human medicines and health products for the protection of Public Health." *See* http://www.infarmed.pt/portal/page/portal/INFARMED/ENGLISH.

Pharmaceutical Benefits Agency (TLV),[13] *available at* http://www.tlv.se/beslut/sok/lakemedel/. The search results are attached as Exhibit 15.

15. Teva, through Ratiopharm,[14] and Ranbaxy, sell a generic Nexium in Austria. These facts are reflected in the 2012 Code of Reimbursement (Erstattugskodex) published by the Main Association of Austrian Social Security Institutions (Hauptverband der österreichischen Sozialversicherungsträger), *available at* http://apps.who.int/medicinedocs/documents/s19463de/s19463de.pdf, and the Amendment to the Code of Reimbursement dated August 30, 2012, *available at* https://www.avsv.at/avi/dokument/dokumentanzeige.xhtml?dokid=2012%3D99&dokStat=0&csrId=3959&tlId=1395762227902. The relevant pages of these documents are attached hereto as Exhibits 16 and 17.

The facts set forth above relating to Teva's and Ranbaxy's launch of generic Nexium are based on: (1) information publically available on databases and publications maintained by governmental agencies that are responsible for monitoring and/or regulating pharmaceutical drugs in their respective countries; (2) databases and publications maintained by companies that monitor or coordinate health care; and/or (3) Teva's filings with the Securities and Exchange Commission. Teva, either directly or through one of its subsidiaries, has launched generic Nexium in Austria, Belgium, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, Portugal, Spain, Sweden, Switzerland and the United Kingdom, and Ranbaxy has launched a generic Nexium in Austria, Finland, France, Italy, Portugal, Spain, and Sweden.

[13] The LTV is a central government agency that determines whether pharmaceutical or dental products should be reimbursed by the state.

[14] Ratiopharm was acquired by Teva in 2010 and is now a subsidiary of Teva. *See* Ex. 3 at 8, 17 and 48.

Conclusion

Accordingly, Plaintiffs respectfully request that the Court deny Defendants' Motion *in Limine* to Exclude Evidence of Foreign Sales of Generic Nexium (ECF No. 1133), or alternatively defer ruling until the issue arises in a concrete way.

Dated: October 26, 2014

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Thomas M. Sobol, hereby certify that I caused a copy of the foregoing document to be filed electronically via the Court's electronic filing system on October 26, 2014. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Respectfully submitted,

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